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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/653,294	05/24/1996	CAROL CLAYBERGER	286002020023	5995

25225 7590 12/30/2002
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EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/30/2002

57

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/653,294

Applicant(s)

Clayberger et al

Examiner

DiBrino, Marianne

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/10/02, 8/23/01, 12/18/01, 2/5/01
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 12, 13, 15-21, and 27 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 12, 13, 15-21, and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. Applicant's amendments filed 6/10/02 (Paper No. 54), 8/23/01 (Paper No. 45), 2/5/01 (Paper No. 39) and 12/18/01 are acknowledged and have been entered.
2. Claims 2-4, 12, 13 and 15-21 and 27 are pending.

Claims 2-4, 12, 13, 15-21 and 27 are presently being examined.

The following new objections and rejections are necessitated by Applicant's said amendments.

3. The amendment filed 12/18/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the peptide sequences corresponding to SEQ ID NO: 40-42.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 2-4, 12, 13, 15-21 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendatory material that is not supported by the disclosure as filed is: the peptide sequences corresponding to SEQ ID NO: 40-42 recited in instant claim 15 and "consists of 12 to 60 amino acids" recited in base claim 27.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 2-4, 12, 13, 15-21 and 27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - a. Claim 15 is indefinite in the recitation of "wherein comprises" because it is not clear what is meant.
 - b. Claim 27 is indefinite in the recitation of "consists of 12 to 60 amino acids, and has the

one of the following structures” because it is not clear what is meant. The SEQ ID NO recited in claim 27 are each 10 amino acid residues in length.

c. Claim 15 is indefinite in the recitation of the peptides with the sequences of SEQ ID NO: 40, 36, 41 and 42 because the peptides lack antecedent basis in the formulae (SEQ ID NO: 38 and 39) recited in base claim 27, i.e., the said peptides do not have the structure recited in the base claim.

d. Claim 17 is indefinite in the recitation of the peptide with the sequence of SEQ ID NO: 36 because the peptide lacks antecedent basis in the formulae (SEQ ID NO: 38 and 39) recited in base claim 27, i.e., the said peptide does not have the structure recited in the base claim.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 2-4, 12, 13, 18-21 and 27 are rejected under 103(a) as being unpatentable over Olsson, U.S. Patent No. 5,073,540 or WO 88/05784 (for the reasons of record in the Office Action mailed 8/16/99, Paper No. 29, as enunciated below).

Olsson discloses peptides useful as antagonists or agonists for membrane receptors. The prior art compounds have essentially the same structure as those of the instant application (especially columns 7 and 8). WO 88/05784 discloses similar peptides (especially claim 1).

WO 88/05784 also suggests modification of such peptides using conventional techniques to extend their biological half lives (especially pages 21-23). Page 10 of the instant application discloses such conventional techniques.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the prior art peptides and to test functional activity on surface receptors or lymphocyte activity of the modified peptides using the assays disclosed in Olsson (especially columns 12-14) or by WO 88/05784 (especially page 25). Further, page 40 of WO 88/05784 explicitly suggests use of such peptides for prolonging graft survival time by reducing rejection caused by CTL. One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to stimulate or inhibit membrane receptors and/or to prolong graft survival time.

Applicant's arguments in the amendment filed 2/5/01 have been fully considered but they are not persuasive.

It is Applicant's position on page 5 of the said amendment that dimers are not taught by the references, nor are inverted dimers. It is Applicant's further position that there is no mention as to what positions would be open to substitution.

It is the Examiner's position that one of ordinary skill in the art would have expected that dimers of the same unit would exert the same functional effects as a monomer. It is noted that the claim language is not limited to palindromic or inverted dimers. It is the Examiner's further position that the art references teach peptides comprising the peptide with the sequence of SEQ ID NO: 38 in instant claim 27, and no teaching of what positions are open to substitution is necessary.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

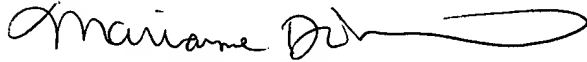
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

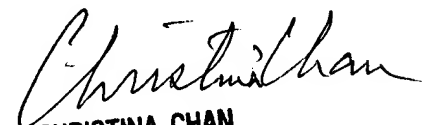
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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



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December 22, 2002



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